



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,559	02/05/2002	C. Grant Willson	5119-07301	6950
7590	03/10/2004		EXAMINER	
ERIC B. MEYERTONS CONLEY, ROSE & TAYON, P.C. P.O. BOX 398 AUSTIN, TX 78767-0398			BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/068,559	WILLSON ET AL.
	Examiner	Art Unit
	William H. Beisner	1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 Aug. 2002 (preliminary amendment).
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24, 50, 76 and 97 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-24, 50, 76 and 97 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 05 February 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 04 Dec. 2002 has been considered and made of record.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is not clear which of the positively recited structures provides the intended function of “the identity of the analyte is determined by the detection of the signal and the shape of the sensing element during use”. Note the reference to the detector merely states that a signal is produced. The claim is devoid of any positively recited structural element for determination and/or detection of “shape” and/or analyte determination in view of the signal and shape.

Claim 24, line 11, “the particle” lacks antecedent basis. It appears that “particle” should be “sensing element” or “sensing elements”. Also the claim does not positively recite the “sensing elements” as part of the claimed device. The claim merely recites, “configured to hold sensing elements”.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 50 is rejected under 35 U.S.C. 102(b) as being anticipated by Heitzmann (US 4,557,900).

The reference of Heitzmann discloses a method for forming a sensor array configured to detect an analyte in a fluid that includes forming a sensing element(s) having a predetermined shape (beads, 15; See column 4, line 64, to column 5, line 3 and column 6, lines 21-29). The sensing elements (15) are placed (blended) with a silicone pre-polymer (liquid composition) and cured to form a supporting member (matrix) (See column 6, lines 30-35).

6. Claims 76 and 97 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al.(JP 9-105747).

With respect to claim 97, the reference of Yamamoto et al. discloses a sensor array (1) that includes a supporting member (2) and a plurality of sensing elements (120,80,60,45,30) coupled to the supporting member (2) wherein the sensing elements comprise a plurality of different shapes (See Figure 2).

With respect to claim 76, the reference of Yamamoto et al. discloses a method of sensing an analyte in a fluid that includes passing a fluid over a sensor array (1). The sensor array including at least one sensing element (120,80,60,45,30) coupled to a supporting element (2). The at least one sensing element has a predetermined shape (See Figure 2). Spectroscopic changes in the sensing element are determined when contacted with a fluid containing an analyte and the shape of the sensing element is also determined (See the English language machine translation attached).

7. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Walt et al.(US 5,512,490).

The reference of Walt et al. discloses a system for detecting at least a first and second analyte in a fluid that includes a light source (100); a sensor array (10) including a supporting member (12) configured to hold sensing elements (20,30,40,50); and a detector (112) configured to detect the signal produced by the interaction of the analyte with the sensing elements during use. The light source (100) and detector (112) are positioned such that light passes from the light source to the sensing elements and onto the detector during use (See Figure 2). While the instant claim language specifies that the sensing elements are of different shape, the instantly claimed structure does not positively recite that the sensing elements are part of the claimed device. The instant claim language merely recites that the supporting member is configured “to hold sensing elements” of the recited configuration. The supporting member disclosed by Walt et al. is capable of holding sensing elements recited in the claim. Further note, while figure 1 of Walt et

al. depicts sensing elements of different shapes, the reference states that these shapes are for illustration purposes only (See column 9, line 57, to column 10, line 8).

8. Claim 97 is rejected under 35 U.S.C. 102(e) as being anticipated by Bodenhamer (US 6,051,388).

With respect to claim 97, the reference of Bodenhamer discloses a sensor array that includes a supporting member (polymer film) and a plurality of sensing elements coupled to the supporting member wherein the sensing elements comprise a plurality of different shapes (See Figure 7).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1744

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-7, 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al.(JP 9-105747) in view of Howard, III et al.(US 5,408,535) and Horikami (US 5,263,098).

With respect to claim 1, the reference of Yamamoto et al. discloses a sensor (1) that includes a support member (2) configured to support one or more sensing elements (120,60,80,45,30) wherein the sensing elements have a predetermined shape (See Figure 2) and wherein the sensing elements are configured to produce a signal when the sensing elements interacts with analyte during use.

Claim 1 differs by reciting that the system includes a light source and a detector positioned such that light passes from the light source to the sensing elements and onto the detector during use.

The reference of Howard, III et al. discloses that it is known in the art to automate the reading of a test strip by using a light source (15,13) and detector system (12,33) for detecting the signal produced by the interaction of the analyte with the sensing elements during use.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a light source and detector system as suggested by the reference of Howard, III et al. with the sensor device of the primary reference of Yamamoto et al. for the known and expected result of reducing the imperfections associated with the use of the naked eye when comparing colors (See column 1, lines 15-49, of Howard, III et al.).

The claim differs further by reciting that the system includes a device for determining the shape of the sensing element.

The reference of Yamamoto et al. discloses that the use of shapes associated with specific sensing elements is known in the art so as to provide a means so as to distinguish between two different analytes that may produce similar color changes (See the English language abstract and machine translation).

The reference of Horikami discloses that it is known in the art to employ image processing to determine the shape of an object present in a captured image (See column 1, lines 1-64).

In view of these disclosures, it would have been obvious to one of ordinary skill in the art to modify the imaging system of the modified primary reference such that the shape of the sensing element can also be determined automatically and would allow complete automation of the detection of analyte using the sensor of Yamamoto et al. as is suggested by the prior art discussed above.

With respect to claim 2, the reference of Howard, III et al. discloses the use of a white light source (15).

With respect to claim 3, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ other known light sources, such as LED or lasers, based merely on the specifics of the reagents employed in the sensing element while maintaining the efficiency of the detection system.

With respect to claims 4 and 5, the reference of Howard, III et al. discloses the use of a CCD camera and filters (See column 5, lines 23-31).

With respect to claim 6, the use of filters to remove background light and/or excitation light is conventional in the art and would have been obvious for the known and expected result of improving the signal-to-noise ratio of the detection system.

With respect to claim 7, the reference of Yamamoto et al. discloses that the support member can be made of a polymer (See paragraph [0017] of the machine translation).

With respect to claim 9, the sensing element is positioned at the surface of the supporting member (See Figure 2).

With respect to claim 15, the support member (2) is a rigid material and the sensing elements are disposed on a surface of the support member (See Figure 2).

13. Claims 8, 11-14, 17, 18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al.(JP 9-105747) in view of Howard, III et al.(US 5,408,535) and Horikami (US 5,263,098) taken further in view of Wohlstadter et al.(US 6,066,448).

The combination of the references of Yamamoto et al., Howard, III et al. and Horikami has been discussed above.

The above claims differ further because they recite the use of polymers and receptors when describing the sensor support member and sensing elements.

The reference of Wohlstadter et al. discloses the use of a sensing array device (See Figures 5A and 5B) wherein each reagent zone includes different binding specificities (receptors) (See column 11, lines 12-55). The reference also discloses that the support member can be made of a polymer material (See column 12, lines 5-12). Furthermore the reference discloses a number of means in which to form the array of binding sites on the support member. The list of techniques includes integrating the receptors into a porous matrix prior to polymerization or gelation (See column 15, lines 3-48).

In view of these teachings and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to manufacture the test strip of the modified primary reference using the known techniques taught by the reference of Wohlstadter et al. for the known and expected result of providing an alternative means recognized in the art for providing an array of sensing elements on a support member such that the sensing elements can be exposed to a sample fluid.

Note the specific receptors and/or reagents employed would have been clearly within the level of one having ordinary skill in the art for the known and expected result of employing specific reagents dependent upon the target analyte that is to be detected.

14. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al.(JP 9-105747) in view of Howard, III et al.(US 5,408,535) and Horikami (US 5,263,098) taken further in view of Mauze et al.(US 6,379,969).

The combination of the references of Yamamoto et al., Howard, III et al. and Horikami has been discussed above.

Claim 16 differs by reciting that the support member includes a well with the sensing element within the well.

The reference of Mauze et al. discloses that it is known in the art to provide a sensing element array in the form of a support member with sensing elements on the surface thereof (See Figure 2) or the support member can be a well plate with the sensing elements within the wells (See Figure 5).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a support member that includes wells for the known and expected result of providing an alternative means recognized in the art to achieve the same result, supporting a sensor array to be contacted with a fluid sample. The use of wells would prevent cross contamination between the test zones in the array.

15. Claims 10, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al.(JP 9-105747) in view of Howard, III et al.(US 5,408,535), Horikami (US 5,263,098) and Wohlstadter et al.(US 6,066,448) taken further in view of Walt et al.(US 5,512,490).

The combination of the references of Yamamoto et al., Howard, III et al., Horikami and Wohlstadter et al. has been discussed above.

While the prior art discussed above discusses the use of a polymer material for forming the sensing element, the instant claims recite the use of a polyethylene glycol polymer.

The reference of Walt et al. discloses that when forming a sensing substrate as shown in Figure 1, it is known to employ polyethylene glycol polymer as a means for immobilization of the detection reagents (See column 27, lines 11-27).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to determine the optimum polymer to employ when immobilizing the test reagents or receptors as suggested by the prior art while maintaining the efficiency of the detection system.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744